APR 3 0 2003

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Rex Medical
585 County Line Road
Radnor, PA 19087

Date Summary Prepared:

November 15, 2002

2. Name of the Device:

Hemo-Stream™ Hemodialysis Catheter Set

3. Predicate Device Information:

K#012365, Vaxcel Dialysis Catheter, Boston Scientific Corporation, Natick, MA.

4. Device Description:

The Rex Medical Hemo-Stream™ Hemodialysis Catheter is a 16F chronic, multi-lumen, radiopaque, polyurethane catheter with a polyester cuff and two female luer locking adapters. The cuff promotes tissue in-growth for fixation of the catheter in a subcutaneous tunnel. The luer locking adapters, as well as the tubing clamps, are colored to differentiate the arterial and venous lumens. Four arterial intake lumens are located 360° around a central venous lumen. The catheter intended purpose is identical to the predicate device with the exception that the Hemo-Stream™ Catheter does not facilitate the use of a tear-away sheath during the insertion procedure. The catheter will be manufactured in useable lengths, or the length from the distal catheter tip to the hub junction, of 24cm, 28cm, 32cm, 36cm, and 40cm.

5. **Intended Use:**

The Hemo-Stream™ Hemodialysis Catheter Set is designed for chronic hemodialysis and apheresis.

6. **Comparison to Predicate Devices:**

Discussion of Similarities:

The Hemo-Stream™ Hemodialysis Catheter is similar to the Vaxcel Catheter in that they both provide access for hemodialysis. Both Catheters offer a color-coded female luer adapter, red for arterial and blue for venous, to attach to a dialysis tubing set. The female luers for both catheters offer the corresponding lumen priming volume to insure the catheter receives the proper heparin lock between treatments. Both catheters offer a fixed polyester felt cuff located on the catheter lumen to stimulate tissue in-growth which will anchor the catheter in place as well as form an infection barrier. Proximal to the catheter lumens for both catheters is an integrated hub that encapsulates the catheter tubing and extension tubing junctions. On this hub is a rotating suture wing that may be used to anchor the catheter to the patient until the tissue in-growth around the catheter cuff is matured. Both catheters are made of a polyurethane material and have an adequate offset distance on the distal tip between the arterial intake lumen and the venous return lumen to reduce the effects of arterial/venous blood re-circulation.

Discussion of Differences

The outer diameter of the Hemo-Stream™ Hemodialysis Catheter is approximately 16F. The proximal portion of the Vaxcel Catheter has an outer diameter of 16F that tapers down to 14F distally. The Hemo-Stream™ Hemodialysis Catheter has four independent lumens for arterial intake and one lumen for venous return. The Vaxcel Catheter has one arterial intake lumen and one venous lumen. The Vaxcel utilized a tear-away sheath for catheter insertion while the Hemo-Stream™ Hemodialysis Catheter provides a catheter stiffener that allows the catheter to be introduced over the guidewire.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Comparative Functional testing to the predicate was performed based on ISO 10555-1 and the FDA's Reviewer Guidance for Long Term and Short Term Intravascular Catheters. Material Testing also included ISO 10993 Biocompatibility Testing. Testing results revealed the subject device to be substantially equivalent to the predicate device.

8. Discussion of Clinical Tests Performed:

Not applicable, as there are no new indications for use which must be supported by clinical data.

9. Conclusions:

The subject device, Hemo-Stream™ Hemodialysis Catheter, has the same intended use as the predicate device, the Boston Scientific Vaxcel Catheter. Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety and effectiveness. Thus, the Hemo-Stream™ Hemodialysis Catheter is substantially equivalent to the predicate device, the Vaxcel Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Rex Medical
c/o Ms. Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd.
Suite 200
GREAT NECK NY 11021

Re: K023847
Trade/Device Name: Hemo-Stream™ Hemodialysis Catheter Set
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: February 28, 2003
Received: May 5, 2003

Dear Ms. Goldstein-Falk:

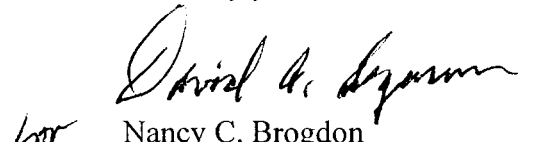
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K02 3847

Device Name: Hemo-Stream™ Hemodialysis Catheter Set

Indications For Use:

The Hemo-Stream™ Hemodialysis Catheter Set is designed for chronic hemodialysis and apheresis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023847